UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION

HARVINDER S. SANDHU, M.D., and KYPHON INC., Plaintiffs, v. MEDTRONIC SOFAMOR DANEK, INC., MEDTRONIC SOFAMOR DANEK USA, INC., and SDGI HOLDINGS, INC., Defendants.	Court File No. 2:05-2863-MI V

KYPHON'S COMBINED OPPOSITION TO MEDTRONIC'S MOTIONS FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY OF U.S. PATENT NO. 5,108,404 BASED ON THE KENNEDY, OLERUD, DICK, AND ROMBOLD REFERENCES

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I. INTRODUCTION

Medtronic's summary judgment motions based on 35 U.S.C. §§ 102 and 103 (D.I. 154 and 173) should be rejected for the same reasons that a near-identical motion was previously rejected by the District of Delaware. Kyphon's '404 patent survived summary judgment of invalidity in a previous litigation based on prior art either identical, or better than, the prior art references asserted by Medtronic. *Kyphon, Inc. v. Disc-O-Tech Medical Technologies, Ltd. and Disc Orthopaedic Technologies, Inc.*, No. 04-204-JJF (D.Del.) (the "Delaware Litigation"). In that earlier motion, Disc Orthopedic Technologies ("DOT") moved for summary judgment of invalidity based on the Edeland and Olerud prior art references. [Kyphon Ex. 60, DOT's Motion for Summary Judgment of Invalidity Based on Anticipation and/or Obviousness.] Medtronic now moves for summary judgment of invalidity based on the Olerud reference and the Kennedy, Dick and Rombold references,[1] which are procedures that are even further afield than the rejected Edeland reference[2] (for instance, Kennedy and Rombold concern fractures of the tibia – the leg – not vertebra). After Kyphon's '404 patent withstood DOT's invalidity challenges on summary judgment, DOT went to trial. But after the infringement phase of the jury trial concluded, DOT chose to abandon the U.S. market—the largest market in the world—and concede the validity of Kyphon's '404 patent, rather than take another day to present its invalidity arguments to the jury.

Kyphon's patented kyphoplasty procedure was revolutionary in 1989, when the '404 patent's parent application was filed. There simply is no prior art that comes close to the invention, and Medtronic has not asserted any prior art materially better than previously asserted by DOT. The prior art relied upon by Medtronic is far from the '404 patent's kyphoplasty procedure in many respects: (1) the references teach invasive "open" procedures that require

[1] Medtronic's initial summary judgment of invalidity motion is based on Dick, Kennedy and Olerud. It subsequently filed a separate motion based solely on the Rombold reference. Kyphon opposes both motions here and addresses all four references put forth by Medtronic.

[2] Medtronic's technical expert opines on the Edeland reference in his declaration, but it is only noted in Medtronic's opposition to Kyphon's request for a preliminary injunction, and is not included at all in Medtronic's summary judgment motion.

cutting open large parts of the patient's body and using substantial external hardware (e.g. screws, fixators, and other implants) to treat the fracture in way significantly different than the minimally invasive kyphoplasty invention claimed in the '404 patent, which brings immediate stability to the fractured bone; (2) these antiquated procedures are not routinely practiced because of their risks; (3) the references either do not teach compaction of bone marrow – rather they teach moving fractured bone back to its pre-fractured place (*i.e.*, "fracture reduction") – or, to the extent they teach any compaction at all, they do not teach enlarging by compaction the initial passage into bone marrow formed by the surgeon; (4) the references do not teach filling of the enlarged passage that is claimed in the second step (the passage created by increasing the volume of the initially formed passage via compaction), and; (5) the references do not disclose a filling material that is both "flowable" and "capable of setting to a hardened condition."

Any one of these differences between the prior art and Kyphon's pioneering invention, as detailed below, compel the denial of Medtronic's motions.

II. MEDTRONIC'S HIGH SUMMARY JUDGMENT BURDEN[3]

Summary judgment can only be granted when all inferences are drawn in favor of the non-movant and there are no genuine issues of material fact. The already-demanding standard for obtaining summary judgment is even more difficult to meet by a party seeking to have a patent declared invalid, because a patent is entitled to a presumption of validity. 35 U.S.C. § 282. This presumption of validity can be overcome only by clear and convincing evidence. *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 715-16 (Fed. Cir. 1991). "Thus, a moving party seeking to invalidate a patent at summary judgment must submit such clear and convincing evidence of invalidity so that no reasonable jury could find otherwise." *Eli Lilly & Co. v. Barr Labs., Inc.*, 222 F.3d 973, 980 (Fed. Cir. 2000).

Medtronic submitted two declarations by Dr. John M. Mathis, an interventional radiologist,[4] in support of its summary judgment motions. [Medtronic Ex. 1, Declaration of John

M. Mathis, M.D., M.Sc. ("Mathis Decl."); and Medtronic Ex. 29, Supplemental Declaration of John M. Mathis, M.D., M.Sc. ("Mathis Supp. Decl.").] Neither of these declarations mentions the "clear and convincing" standard. Further, Dr. Mathis testified has not heard the terms "burden of proof" or "clear and convincing evidence," and he does not have an understanding of what the phrase "clear and convincing" evidence means in the context of this case. [Kyphon Ex. 58, Mathis Depo. Tr. at 67:21-68:7.]

III. THE LAW OF ANTICIPATION

A prior art reference anticipates a claim if it discloses each and every claim limitation, either expressly or inherently. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1377 (Fed. Cir. 2003); *EMI Group No. Am., Inc. v. Cypress Semiconductor Corp.*, 268 F.3d 1342, 1350 (Fed. Cir. 2001). If an element is not expressly disclosed in the prior art reference, the reference may still anticipate if the missing element is "necessarily" present in the thing described in the reference. *Schering Corp.*, 339 F.3d at 1378. The overarching requirement of inherent anticipation is that the invention being claimed must "necessarily" and "inevitably" result in the practice of the prior art reference. *Id*. Inherent anticipation requires that the missing element is "necessarily present, not merely probably or possibly present, in the prior art." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295 (Fed. Cir. 2002) (internal quotations omitted); *Rosco, Inc. v. Mirror Lite Co.*, 304 F.3d 1373, 1380 (Fed. Cir. 2002) (any inherently present claim must be "necessarily present," nor merely probably or possibly present). As the Federal Circuit stated, "[o]cassional results are not inherent." *MEHL/Biophile Int'l Corp. v. Milgraum*, 192 F.3d 1362, 1365 (Fed. Cir. 1999). Thus, the mere fact that a certain thing may

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[3] For a more complete discussion of the legal standards for invalidity and summary judgment, see section II.A and II.B of Kyphon's Opposition to Medtronic's §112 summary judgment motion, filed concurrently with this brief.

[4] Dr. Mathis testified that he has performed kyphoplasty, the procedure claimed in the '404 patent, on only two or three vertebral bodies of one or two live human patients. [Kyphon Ex. 58, Mathis Depo. Tr. at 28:17-29:6.] The last one he performed was in about 1998. [*Id*. at 27:8-16.] He further testified that he has never performed any procedure similar to those described in any of the five references discussed in his declaration. [*Id*., Mathis Depo. Tr. at 38:14-18.]

result from a given set of circumstances is not sufficient for inherent anticipation. *In re Oelrich*, 666 F.2d 578, 581 (C.C.P.A. 1981).

Neither of Medtronic's summary judgment motions expressly argues that a limitation of the '404 is inherently anticipated in any of the asserted prior art references. And, Dr. Mathis's declaration does not accurately and precisely state the law on inherent anticipation. Instead, Dr. Mathis's declaration states that "[a] prior art reference may anticipate a claim by inherency if an element is not expressly stated, but is necessarily in an embodiment of the invention described in the prior art reference" and cites only to Section 102 (which says nothing about inherency). [Medtronic Ex. 1, Mathis Decl. at ¶ 7.] Dr. Mathis admitted that he did not write that sentence in his declaration and his testimony made it clear that he does not have a clear understanding of what inherency requires. [Kyphon Ex. 58, Mathis Depo. Tr. at 69:3-20.] In particular, Dr. Mathis did not understand that inherent anticipation requires that an element not expressly stated must be "***necessarily***" and "***inevitably***" be present in every case or instance. [*Id*. at 70:15-19.] Indeed, for certain prior art references and certain claimed limitations, Dr. Mathis testified only that certain claimed limitations of the '404 patent "could be" or "may" be present in the written disclosure of the reference, or that the reference "implied" that the limitation was present. But—critical to inherent anticipation—he never testified that a claimed limitation that was not expressly disclosed was "necessarily" and "inevitably" present in the reference. *See Schering Corp.*, 339 F.3d at 1378.

IV. KYPHON'S RESPONSE TO MEDTRONIC'S "STATEMENTS OF UNDISPUTED FACTS"

Kyphon objects to many of the facts that Medtronic claims to be "undisputed" and upon which its motions are based, precisely because they are disputed facts that preclude the granting of summary judgment. Medtronic, for example, alleges that the ultimate question as to whether the cited prior art references anticipate or make obvious claims 1 and 12 of the '404 patent is undisputed. As detailed below, Kyphon contends, and provides copious supporting evidence, that the cited references do not teach all the limitations of the claims at issue. Thus, Kyphon

clearly disputes Medtronic's arguments that these references invalidate Kyphon's patent. Kyphon responds to Medtronic's Statements of Facts on a paragraph-by-paragraph in attached Appendix A, and the most important disputes are noted here.

For instance, Medtronic says that the definition of "bone marrow" is "undisputed," but interprets the term to exclude cancellous bone, even though Kyphon's Preliminary Injunction application clearly states that "bone marrow" should be construed here as it was construed by the District of Delaware: "a combination of the connective tissue and the cancellous bone framework inside a bone." [Medtronic Ex. 24, Delaware Litigation May 16, 2005 claim construction order at 12; Kyphon Ex. 35, Marks Decl. at ¶ 11.]

Likewise, Medtronic says that is "undisputed" that the cited references teach all three method steps of claim 1 of the '404 patent. But, none of the prior art references teach step 2 or 3 – the "compaction" and "filling" step. With respect to the compaction step, the references Medtronic relies upon do not teach: (1) initially forming a passage, and (2) subsequently increasing the volume of ***that*** initial passage by compaction. They also do not teach the filling step because they do not disclose filling the particular "passage" formed in the preceding limitation, or disclose a filling material that is both "flowable" and "capable of setting to a hardened condition."

V. CLAIM CONSTRUCTION

The first step in assessing a patent's validity is claim construction. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1456 (Fed. Cir. 1998) (*en banc*); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995). The '404 patent has already been construed in the Delaware Litigation. [Medtronic Ex. 24, Delaware Litigation May 16, 2005 claim construction order.] While not binding on this Court, Kyphon contends that this interpretation was fully litigated, is fully supported by the intrinsic evidence, and is thus correct. To the extent that any relevant claim term was not construed by the Delaware court, Kyphon urges this Court to apply its plain and ordinary meaning. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*) (claim terms are generally given their customary and

ordinary meaning, which is the meaning the term would have to a person of ordinary skill in the art in question at the time of the invention).[5]

VI. NONE OF THE CITED REFERENCES INVALIDATES THE '404 PATENT

Claim 1 of the '404 patent is the only independent claim at issue and reads as follows:

> 1. A method of fixation of fracture or impending fracture of a bone having bone marrow therein comprising:
>
> forming a passage in the bone marrow;
>
> compacting the bone marrow to increase the volume of said passage; and
>
> filling the passage with a flowable material capable of setting to a hardened condition.

The court in the Delaware Litigation construed the disputed terms as follows:

'404 Patent Claim 1	Construction
bone marrow	a combination of the connective tissue and the cancellous bone framework inside a bone
forming a passage in the bone marrow	forming a channel in the bone marrow
compacting the bone marrow to increase the volume of said passage	compacting the bone marrow to increase the volume of the created channel
flowable material capable of setting to a hardened condition	filling the created channel with a material that is capable of flowing into the channel and of setting to a hardened condition

[Medtronic Ex. 24, Delaware Litigation May 16, 2005 claim construction order at 12.]

Claim 12 of the '404 patent reads as follows:

> 12. A method as set forth in claim 1, wherein the fracture is a fracture of a vertebral body of the human spine.

All the dependent claims of the '404 patent include the limitations of claim 1. Thus, if claim 1 is not shown to be invalid by clear and convincing evidence, then summary judgment of anticipation must be denied with regard to claim 12 as well.[6]

[5] Dr. Mathis has not formed an opinion as to whether the claims are invalid using a claim construction different than what he understands to be Kyphon's construction. [Kyphon Ex. 58, Mathis Depo. Tr. at 55:9-56:2.]

None of the references cited in Medtronic's motions for summary judgment of invalidity meets every limitation of claim 1. Therefore, summary judgment of anticipation of independent claim 1 and dependent claim 12 based on any of these references must be denied. In addition, Kennedy and Rombold describe procedures in the leg, so for that additional reason they cannot invalidate claim 12, which is limited to vertebra.

VII. DICK DOES NOT ANTICIPATE THE '404 PATENT

The Dick reference is a three page description,[7] of an invasive open procedure whereby an internal fixator, pictured below, that is screwed into the healthy vertebrae surrounding the fracture is used to initially reduce the fracture, i.e, raise the end plates of the fractured bone. [Kyphon Ex. 43, Dick book at 66-70.] After the fixator creates a void in the fractured bone, via reduction, a window is formed in the pedicular cortical bone of the fractured vertebra into the interior of the bone. [*Id*. at 46.] A small bent impactor can be introduced through this window into the vertebral body to achieve further reduction. Small bone fragments are then pushed by a device that is inserted through the window. Dick explains that the metal implants, such as screws and rods, are used for immediate stability of the fractured vertebra, and in addition, fusion[8] of healthy vertebrae surrounding the fractured vertebra is almost always performed. [*Id*.] According to Dick, nine to twelve months after the surgery is a suitable time for removal of the metal work. [*Id*.]

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[6] Moreover, dependent claims must be invalidated independently, should the independent claim from which they depend be invalidated. *Schumer v. Lab. Comp. Sys., Inc.,* 308 F.3d 1304, 1316-17 (Fed. Cir. 2002).

[7] The relied upon reference is a portion of a 200-page book that reports on many different medical procedures. [Kyphon Ex. 58, Mathis Depo. Tr. at 71:4-14.] The book, as well as the other references, was brought to Dr. Mathis's attention by Medtronic's counsel. [*Id*. at 71:15-18, 39:22-40:6.] He did not conduct an independent search for prior art references. [*Id*. at 40:7-11.]

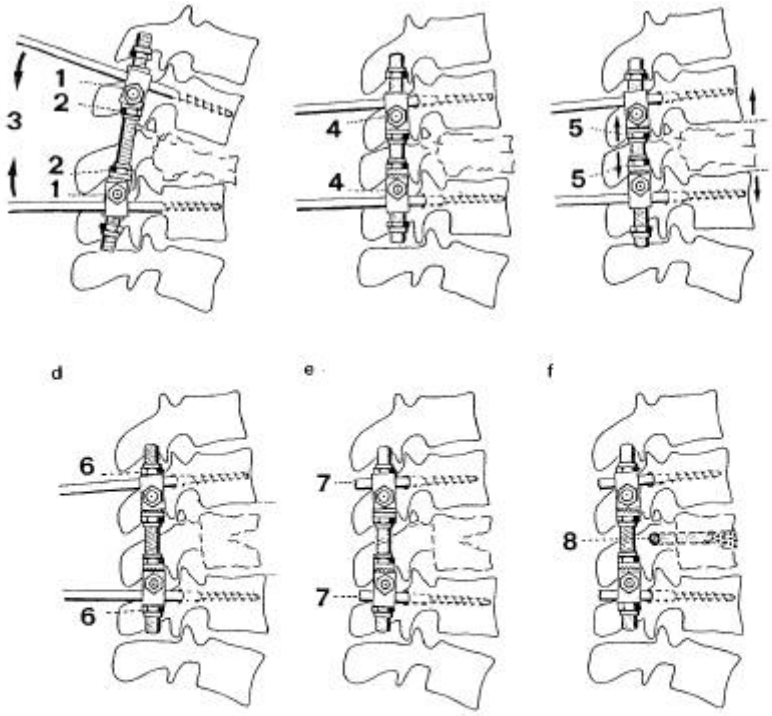

Fig. 60. Schematic representation of steps for reduction of the fracture.

a) Initially the kyphosis must always been corrected by approximating the ends of the Schanz screws (3). The lateral nuts (1) on the clamp elements are loose, the distraction nuts (2) are at a defined distance from the clamp elements or are quite loose depending on the state of the posterior wall of the vertebra (see text).
b) Tightening of the lateral nuts (4). This results in angular stability.
c) Distraction with the distraction nuts (5) in order to restore the anatomical height of the vertebra.
d) Tightening of the counter nuts (6), which results in rotational stability.
e) Removal of the projecting ends of the Schanz screws (7) with special bolt cutter.
f) Transpedicular cancellous bone grafting.

[*Id.*, Dick book at 67.]

The steps Dick can be summarized as follows:

[8] Fusion involves fusing two bony segments together so that motion at that point is eliminated.

1. A fractured vertebra that requires intervention by the surgeon has had part of its hard outer bone shell (the cortical bone) already crushed down by the fracture, which compresses much of the inner cancellous bone inside the vertebra.

2. A metallic fixator device is attached via screws to the vertebrae above and below the fracture site. The fixator is then used to stretch the fractured vertebra back toward its original shape. In doing so, a cavity is created within the body of the vertebra.

3. The surgeon drills a hole in the pedicle of the fractured vertebra to access the already-existing cavity.

4. A probe—essentially a blunt metal stick with a slight curve to it—can be inserted through the hole in the pedicle.

5. The probe pushes up against the crushed cortical bone to move the outer bone back into place, reduce the fracture, and further create a cavity within the body of the vertebral bone.

6. The inner cancellous bone, which had been crushed by the fracture to begin with, stays where it is. Moving the outer bone back into its place with the probe therefore leaves a hole in the vertebra caused by pushing the upper portion of the outer bone away from the lower part.

7. A funnel is inserted into the hole in the pedicle drilled by the surgeon, and bone fragments are pushed through the funnel and into the hole inside the vertebra.

Dick nowhere describes the minimally invasive, percutaneous (through small incision in the skin) kyphoplasty techniques of forming a passage in the bone, compacting bone marrow to increase the volume of that passage formed by the surgeon and thereby creating a compacted cavity that is then filled with a flowable material that hardens to support the repaired vertebra. [Kyphon Ex. 35, Marks Decl. ¶¶ 58-61.]

Dick's use of a probe—called a "slightly bent impactor"—to attempt further reduction of the fractured bone of the vertebra does not teach increasing the volume of the passage into the vertebra initially formed by the surgeon. And Dick's *pushing* bone graft/paste into the vertebrae does not teach the filling of a compressed cavity inside a vertebra with "a flowable material capable of setting to a hardened condition." Indeed, bone graft/paste does not set. [*Id.*, Marks Decl. ¶ 70.]

There are at least two limitations of claim 1 missing from Dick that preclude granting summary judgment of anticipation:

- compacting the bone marrow to increase the volume of the passage first formed in the bone marrow by the surgeon, and
- filling the passage with a flowable material capable of setting to a hardened condition

A. Dick Does Not Disclose Compacting the Bone Marrow to Increase the Volume of the Passage First Formed in the Bone Marrow By the Surgeon

For the "compacting" step, Medtronic relies upon Dick's disclosure that a "slightly bent impactor" ***can*** be introduced into the fractured vertebra through the pedicle to press the cancellous bone within the vertebra against the end plates and anterior wall. [Medtronic Ex. 1, Mathis Decl. ¶32; Kyphon Ex. 58, Mathis Depo. Tr. at 72:22-73:15.] This is a description of fracture reduction, *i.e*. moving the fractured bone back to its pre-fractured position. [Kyphon Ex. 58, Mathis Depo. Tr. at 75:11-77:2.] Even if Dick discloses the initial formation of the claimed passage (by drilling the pedicle), it does not disclose compacting cancellous bone in that claimed passage. Even Dr. Mathis, Medtronic's own expert, testified that the only "passage" that is enlarged by the Dick impactor is in the interior of the vertebral body. [*Id*., Mathis Depo. Tr. at 75:11-18.] Yet, this area is a cavity in the body portion of the vertebral bone that results from the initial reduction of the fracture (stretching the fractured vertebra toward its original position) via use of a large metallic fixator – it is not the passage made by the surgeon to access the cavity. Also, Dr. Mathis agreed that Dick did not teach that the bone marrow in the pedicle gets compacted as a result of the impactor's insertion. [*Id*. at 74:23-75:5.]

Dick, therefore, does not teach the sequential steps required by independent claim 1: (1) initially forming a passage, and (2) subsequently increasing the volume of ***that*** initial passage by compaction. [Kyphon Ex. 35, Marks Decl. ¶ 58-60.]

At this stage, especially given Dr. Mathis's admissions during his deposition, it would appear that the Court already has the basis to conclude that Dick does not anticipate as a matter of law. At a minimum, however, the presence of a triable issue of fact is clear: a jury should decide, based on all the relevant evidence, whether Dick discloses the formation of a passage in the bone marrow that is subsequently increased in volume by compaction of the bone marrow, and is entitled to hear that even Medtronic's own expert believes it does not. *See Rockwell Int'l Corp. v. United States*, 147 F.3d 1358, 1366 (Fed. Cir. 1998) (denying summary judgment of

anticipation and noting that there was a question of fact as to whether the asserted prior art reference disclosed the claimed invention).

B. Dick Does Not Disclose "Filling the Passage With a Flowable Material Capable of Setting to a Hardened Condition"

Dick also does not disclose the last limitation of claim 1 of the '404 patent. The construction of this limitation, accepted by Medtronic for purposes of its summary judgment motion, is "filling the created channel with a material that is capable of flowing into the channel and of setting to a hardened condition." [Medtronic Ex. 24, Delaware Litigation May 16, 2005 claim construction order at 12.] This limitation thus requires three elements:

- filling the passage identified in the preceding limitation (*i.e.*, the passage created by increasing, via compaction, the volume of the initially formed passage) with a material that is both:
- capable of flowing into the channel, and
- capable of setting to hardened condition.

The filling taught by Dick does not satisfy any of these three requirements.

1. Bone graft is not a "flowable material capable of setting to a hardened condition"

The filler material disclosed by Dick is autologous bone graft/paste – bone tissue harvested from another part of the patient. [Medtronic Ex. 1-G, Definition of "autograft" in Dorland's Medical Diction at 170.] Medtronic does not actually assert that bone graft/paste is a "flowable material capable of setting to a hardened condition." Nor could it credibly do so, as a typical "flowable material that sets to a hardened condition" is bone cement, not bone graft from the patient. Similarly, Dr. Mathis's declaration also does not independently opine that bone graft is a material that is "flowable" and "capable of setting to a hardened condition."[9] Rather, Medtronic argues only that Kyphon's own patents "admit" that bone graft is a "flowable material

[9] Dr. Mathis's testimony as to his understanding of bone graft is unclear. He testified that bone graft is a material that is used for insertion into bone and would include in that category material which is not itself bone. [Kyphon Ex. 58, Mathis Depo. Tr. at 41:16-42:11.] But, he also testified that bone graft is bone material taken from another part of a patient. [*Id.* at 44:12-17; Medtronic Ex. 1, Mathis Decl. at ¶ 34.] Dr. Mathis has never personally used bone graft, defined as bone material taken from another part of the patient. [Kyphon Ex. 58, Mathis Depo. Tr. at 45:8-12.]

capable of setting to a hardened condition" and therefore Dick discloses the "filling" limitation. Medtronic provides no further evidence or argument other than pointing to Kyphon's patents. Simply put, Medtronic reads way too much into Kyphon's patentsbone graft is not "flowable"

Autologous bone graft/paste is not a flowable material as correctly noted by Dick itself. [Kyphon Ex. 35, Marks Decl. at ¶ 61.] Dick describes "bone graft" as consisting of "small fragments, " "small pieces," or "finely ground" bone, and as optimally having a "paste-like consistency." [Medtronic Ex. 1-F, Dick reference at 46, 70-71.] It further states that these fragments are "***pushed***" with a probe through a funnel into the defect and instructs that "[c]are is taken to ***push*** the graft into the anterior part of the vertebral body." [*Id*. at 70 (emphasis added).] Dick's description of the disclosed material is far from what a person of ordinary skill would consider a "flowable" material.[10]

In fact, the declaration of Dr. Mathis, Medtronic's technical expert, filed in support of Medtronic's motion does not affirmatively assert that bone graft is "flowable." With respect to Dick's disclosure, he merely testified that because bone graft "*should be* paste-like in consistency[, t]hat *implies* to me that it *should be* flowable." [Kyphon Ex. 58, Mathis Depo. Tr. at 80:1-2 (emphasis added).] Dr. Mathis took this position despite Dick's disclosure that the bone graft is "pushed." Dr. Mathis did not testify that the disclosed bone graft is necessarily and inevitably flowable. *Schering Corp.*, 222 F.3d at 1378. Indeed, Dr. Mathis has not formulated a definition of what the term "flowable" means in the context of the '404 patent. [*Id*. at 82:25-83:7.] All of the evidence is that bone graft is not "flowable" as that term is ordinarily used. [Kyphon Ex. 35, Marks Decl. ¶¶ 61, 68-70.] And the opinion of Kyphon's expert, Dr. Michael Marks, is consistent with this evidence. Bone graft that must be pushed into place as described by Dick, is not "flowable." [Kyphon Ex. 35, Marks Decl. ¶ 61.]

[10] *See e.g.,* Kyphon Ex. 43, Dick book at p.237, Figs. 4(b), 4(c) (picture of bone graft from the book that includes the Dick reference relied upon by Medtronic).

a. bone graft is not a material "capable of setting to a hardened condition"

Bone graft is also not capable of *setting* to a hardened condition. [*Id*., Marks Decl. ¶¶ 57, 61, 68-70.] In opining that this element is satisfied, Dr. Mathis relied solely on remarks made in some of Kyphon's patents that are not at issue in this motion.[11] [Kyphon Ex. 58, Mathis Depo. Tr. at 112:19-23.] Dr. Mathis stated that based on the materials he reviewed it seemed to him that Kyphon's and Dr. Mark Reiley's[12] opinion is that bone graft is capable of setting to a hardened condition. And, although he conclusorily stated that he thinks bone graft is capable of setting to a hardened condition,[13] he was not able to establish the basis for his opinion. For example, he did not review any medical texts or dictionaries of any kind for a description of the process by which the body incorporates bone graft. [*Id*., Mathis Depo. Tr. at 85:16-20.] He also was not familiar with terms generally used with bone graft, such as "substitution" and "vascularization." [*Id*. at 85:22-86:10.]

Bone graft itself does not offer any stability to the treated bone. Instead, the body incorporates bone graft into new bone and it is only then when the treated bone is stabilized. [*Id*., Mathis Depo. Tr. at 89:8-20.] As Medtronic's own patents explain with respect to allograft and autograft bone graft:

> Both allograft and autograft are biological materials which are replaced over time with the patient's own bone, via the process of creeping substitution. Over time a bone graft virtually disappears unlike a metal implant which persists long after its useful life.

[Kyphon Ex. 39, U.S. Patent No. 6,371,988 at 2:45-49 ("Medtronic's '988 patent"); Kyphon Ex. 38, U.S. Patent No. 6,261,586 at 2:48-52 ("Medtronic's '586 patent"). Because it takes a significant amount of time for this to happen, bone cavities filled with bone graft do not offer

[11] This argument is addressed at page 14-15, below.
[12] Dr. Mark Reiley is a named inventor on the '404 patent.
[13] Dr. Mathis testified that if bone graft was left out on a table it would dry the same way that wallboard would if one mixed it up with water and put it one the table and let it dry. [Kyphon Ex. 58, Mathis Depo. Tr. at 112:3-7.]

immediate stability to the fractured bone and the bone graft does not "set" to a "hardened condition" like bone cement does.[14] As Medtronic itself explains in its own patents:

> Graft alone may not provide the stability required to withstand spinal loads. Internal fixation can address this problem but presents its own disadvantages such as the need for more complex surgery as well as the disadvantages of metal fixation devices.

[Kyphon Ex. 39, Medtronic's '988 patent at 3:31-34; Kyphon Ex. 38, Medtronic's '586 patent at 3:33-38.]

Indeed, in Dick, immediate stability of the fractured bone is ensured by attaching a metal fixator to the spine and a plaster jacket or full contact corset is described as being required as additional fixation for three or four months post-operatively. [Medtronic Ex. 1-F, Dick at 46, 70; Kyphon Ex. 58, Mathis Depo. Tr. at 87:10-90:3, 97:7-98:10.][15]

b. Medtronic misreads Kyphon's patents, which do not describe bone graft as either being "flowable" or "capable of setting to a hardened condition"

Given that (i) bone graft does not flow like bone cement and does not set like bone cement, and (ii) Medtronic and its experts themselves are unwilling to affirmatively take the position that bone graft does flow or does set, the only "evidence" to the contrary is Medtronic's suggestion that Kyphon has already admitted, in other patents, that bone graft does both of these things. Medtronic's reliance on Kyphon's patents is misplaced. First, as a technical matter, the cited patents are not prior art to the '404 patent. The meaning of "flowable material capable of setting to a hardened condition" is based on the view of a person of ordinary skill at the time of the '404 invention. *See Phillips*, 415 F.3d 1303 ("the ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application") (citations omitted). Thus, any reference dated after February 9, 1989, is irrelevant to this

[14] Dr. Mathis did admit that bone graft ends up being different from polymethylmethacrylate (bone cement). [*Id.*, Mathis Depo. Tr. at 110:14-15, 112:23-113:3.]

[15] A fixator is not used in a kyphoplasty procedure [Kyphon Ex. 58, Mathis Depo. Tr. at 103:1-4], precisely because the bone cement immediately sets into a hardened condition to support the patient's weight.

invalidity analysis.[16] More importantly, none of Kyphon's patents describe "bone graft" as a either a "flowable" material or as a material "capable of setting to a hardened condition." Medtronic's motion refers only to U.S. Patent No. 6,607,544 ("the '544 patent").[17] Medtronic points to the following excerpt:

> It may be indicated, due to disease or trauma, to compress cancellous bone within the vertebral body. The compression, for example, can be used to form an interior cavity, which receives a filling material, e.g., ***a flowable material that sets to a hardened condition, like bone cement***, allograft tissue, autograft tissue, hydroxyapatite, or synthetic bone substitute, as well as a medication, or combinations thereof, to provide improved interior support for cortical bone or other therapeutic functions, or both.

[Medtronic Ex. 1-H, '544 patent at 2:66-3:7 (emphasis added); Medtronic's Initial Memorandum at 14.]

The cited portion of the '544 patent thus states that a "filling material" can consist of one of the following: a flowable material that sets to a hardened condition, allograft tissue, autograft tissue, hydroxyapatite, synthetic bone substitute, a medication, or combinations thereof. [*Id.*] The "flowable material that sets to a hardened condition" example is the only one in the list that is modified by the dependant phrase "like bone cement." Indeed, reading this paragraph in this manner is the only way to honor its syntax. If Medtronic's reading were correct, all of the other materials listed, including hydroxyapatite, would also be flowable materials capable of setting. Yet the '544 patent itself later clarifies that hydroxyapatite is not flowable, but instead *is a solid:* "Another exception lies in the use of an expandable structure 56 to improved insertion of *solid*

[16] For example, the '544 patent was filed on October 19, 1999, and issued on August 19, 2003, much later than the relevant date here. Given its date, the '544 is irrelevant to this invalidity analysis.

[17] In his declaration , Dr. Mathis, Medtronic's invalidity expert, cites to several other Kyphon patents with language similar to that in the '544 patent. These arguments are addressed in Kyphon Ex. 36, Second Declaration of Dr. Harvinder Sandhu at ¶¶ 27-30. As Dr. Sandhu notes, the other patents provide only bone cement as an example of a material that sets to a hardened condition. For example, one of the patents relied upon by Dr. Mathis, the '054 patent states: "The material can comprise medication **or** a material that sets to a hardened condition e.g., bone cement, **or** autograft tissue, **or** allograft tissue, **or** synthetic bone substitute, **or** combinations thereof." [Medtronic Ex. 1-I, the '054 patent at 3:18-21 (emphasis added).]

materials in defined shapes, *like hydroxyapatite* . . ." [*Id*., '544 patent at 13:29-31 (emphasis added).]

Medtronic's argument is thus without merit. Since it has no other evidence on this point, Dick cannot anticipate for this reason alone.

C. Dick Does Not Teach Filling the Claimed "Passage"

Lastly, the void that is filled in Dick is the result of the impactor pushing the cortical bone and reducing the fracture by moving the cortical bone endplates away from each other. A void is thus created as the end plates are raised to their pre-fracture position away from the cancellous bone that had been crushed by the fracture itself. Thus, the void is not the result of a cavity that is formed by increasing the volume of the passage initially formed by the surgeon, which Medtronic and Dr. Mathis say instead is the passage drilled in the pedicle.[18] In addition, the filling material is not introduced into a cavity formed by the claimed compaction step because there is no compaction as claimed either in the pedicle passage or in the vertebral body itself. [Kyphon Ex. 35, Marks Decl. ¶ 61.]

In sum, Dick's bone graft is not "flowable" because it does not have a fluid-like consistency, and it does not "set to a hardened condition." Nor is it used to fill the "passage" described and claimed in the '404 patent or even the passage identified by Medtronic and its expert. On these bases, as well as the others outlined above, Kyphon respectfully submits that Dick does not come close to anticipating its invention claimed in the '404 patent.

VIII. KENNEDY DOES NOT ANTICIPATE THE '404 PATENT

[18] Dick states "A slightly bent impactor can then be introduced into the vertebral body through the pedicle and the cancellous bone within the vertebrae is pressed against the end plates and against the anterior wall of the vertebra so that a central cavity is formed." [Medtronic Ex. 1-F, Dick at 46 (emphasis added).] Yet, Dick also states that a cavity is first formed in the vertebral body via use of a metallic fixator device that is used to stretch the fractured vertebra back toward its original position (before the surgeon drills a passage and before the probe is inserted into the vertebra). [*Id*. at 66 ("reduction of the fracture is performed using the internal fixator"); *id*. at 70 ***"[t]his leaves a large ventral defect after reduction***, and an integral part of the fixator instrumentation is the filling of ventral defects with autologous bonegraft." (emphasis added).]

Kennedy is a four-and-a-half page article describing a method of treating displaced or depressed fractures of the tibial condyle, the name for the top plane of the tibia (the larger bone in the lower leg) just below the knee. The procedure disclosed in Kennedy is an open procedure in which methylmethacrylate—a kind of bone cement—is inserted into the bone through a window cut in the cortical bone. [Kyphon Ex. 58, Mathis Depo. Tr. at 103:13-15.] Metal rods and screws are implanted to stabilize the fractured bone because the procedure itself does not. As Kennedy notes, "the methylmethacrylate filling the cavity has little strength in holding the split fragments together." [Medtronic Ex. 1-M, Kennedy at 154.] Kennedy describes the possible use of a small, blunt instrument (probe) to reduce the fracture by inserting the instrument through a window in the cortical bone and pushing the depressed cortical bone fragments back into their proper place. The probe does not form a passage that is subsequently increased in volume. Finally, while Kennedy does disclose the use of bone cement, the reference does not disclose the use of bone cement in a "flowable" state.

The steps of Kennedy can be summarized as follows:

1. A window (called a "fenestration") is cut into the hard cortical side of the leg bone so that the crushed hard outer bone at the top of the tibia can be seen and manipulated.

2. Through the window in the bone, a probe can be inserted to push the depressed bone fragments back into place.

3. Because the cancellous bone beneath the lifted bone was crushed/compressed from the fracture, lifting the hard cortical bone off of it leaves a void.

4. That void is filled with methylmethacrylate.

There are thus at least three limitations of claim 1 missing from Kennedy that preclude granting summary judgment of anticipation:

- forming a passage in the bone marrow
- compacting the bone marrow to increase the volume of the said passage, and
- filling the passage with a flowable material capable of setting to a hardened condition

A. Kennedy Does Not Disclose "Forming a Passage in the Bone Marrow" or "Compacting the Bone Marrow to Increase the Volume of Said Passage"

As with Dick, Kennedy describes inserting a probe into a bone and reducing the fracture by pushing up the depressed bone fragments. And like Dick, the probe does not: (1) form a passage in the bone marrow and then (2) increase the volume of *that* passage. [Kyphon Ex. 35, Marks Decl. ¶ 50-51.]

For the "formation" step, Medtronic points to Kennedy's discussion of fashioning a window in the cortical bone through which the depressed fractured segments can be visualized and manipulated. [Kyphon Ex. 58, Mathis Depo. Tr. at 104:18-105:2; Medtronic Ex. 1-M, Kennedy at 154.] Forming a window in the cortical bone has nothing to do with forming a passage in bone marrow. Medtronic itself distinguishes between cortical bone and bone marrow. [Medtronic Statement of Undisputed Fact No. 1.] By Medtronic's own admission then, Kennedy's discussion of forming a window in the cortical bone does not meet the "forming a passage in the bone marrow" step.

Kennedy never specifically discusses compacting or compressing bone and the teaching contained within the reference does not disclose that compaction or compression is necessarily and always taking place. [Kyphon Ex. 58, Mathis Depo. Tr. at 105:20:106:16, 106:23:107:9.] Such a disclosure, either express or inherent, is required by law for anticipation. *Schering Corp.*, 339 F.3d at 1378. Most importantly, Kennedy does not teach enlarging the passage Medtronic and Dr. Mathis rely upon for the "forming" step – the window formed in the tibia. [*Id.*, Mathis Depo. Tr. at 105:12-16.] Accordingly, and critical to claim 1, Kennedy does not teach the steps of: (1) forming a passage, and (2) subsequently increasing the volume of ***that*** passage by compaction. [Kyphon Ex. 35, Marks Decl. ¶ 51.]

B. Kennedy Does Not Disclose "Filling the Passage With a Flowable Material Capable of Setting to a Hardened Condition"

Kennedy also does not teach a "flowable material." Kennedy does disclose the use of bone cement, specifically methylmethacrylate, but it does not disclose the use of bone cement in a flowable state.[19] Instead, in Kennedy, the bone cement has to set to a non-flowable texture so

[19] That Kennedy elects to fill the cavity with methylmethacrylate rather than a bone graft shows that Kennedy distinguished the two materials. And, just because a material can be used as a

that rather than flow away from the fracture, it can be physically wadded up and packed into the space at the top of the tibia. [*Id*., Marks Decl. ¶ 52.] It is in fact impractical to use bone cement in a flowable state for this procedure. [*Id*..]

C. Kennedy Does Not Teach Filling the Claimed "Passage"

Also, as with Dick, the space that is filled with methylmethacrylate results from fracture reduction, *i.e*. putting the fractured bone back into its proper place leaves a hole where the fractured bone was before it was lifted. As Kennedy states, "once the articular fragments [have] been put in their proper place an obvious cavity was present in the subarticular bone." [Medtronic Ex. 1-M, Kennedy at 154.] Importantly, the space is not the result of increasing the volume of the initially formed passage—the window formed in the cortical bone. [Kyphon Ex. 35, Marks Decl. ¶ 51.]

D. Kennedy Does Not Make Obvious Claim 12 of the '404 Patent

Claim 12 limits the treatment method of claim 1 to the "fracture of a vertebral body of the human spine." Kennedy is directed to fractures of the tibia and does not refer to the spine or vertebra. [Kyphon Ex. 58, Mathis Depo. Tr. at 127:15-24.] Thus, it cannot anticipate claim 12 because, aside from missing the limitations of claim 1, it is also missing claim 12's limitation of being directed to a vertebral body.

Medtronic also alleges that claim 12 is obvious in view of the Kennedy reference when combined with Dick.[20] Obviousness under 35 U.S.C. § 103 is a legal conclusion based on

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filling material in a bone cavity does not mean it is covered by the '404 patent. Rather, the '404 patent claims a specific type of filling material, one that is both "flowable" and "capable of setting to a hardened condition."

[20] Medtronic relies on the Dick reference to allege that one of ordinary skill would have known to apply the Kennedy procedure on a vertebral body, but that is far from true. Dick does not expressly refer to the Kennedy reference. [Medtronic Ex. 1-F, Dick.] Moreover, at most the Dick reference says that the principle of filling a bone defect resulting from an injury, through a cortical window, *can be* used in vertebral compression fractures. [*Id*., Dick at 46.] It does not teach that any and every procedure for treating tibial fractures, such as the Kennedy procedure, should be used on vertebral compression fractures. On this basis alone, therefore, Kyphon contends that there are genuinely disputed facts that Kennedy does not render claim 12 of the '404 patent invalid under § 103 and Medtronic's motion for summary judgment on this basis should be denied.

underlying factual inquiries: (1) the scope and content of the prior art; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *See Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966). The obviousness inquiry is "highly fact-specific by design," *In re Ochiai*, 71 F.3d 1565, 1569 (Fed. Cir. 1995), and includes examining "what a prior art reference teaches, whether a reference provides a motivation to combine its teachings with others, whether the invention experienced commercial success, and whether it satisfied a long-felt, but unmet need." *Tec Air, Inc. v. Denso Mfg. Mich.*, 192 F.3d 1353, 1359 (Fed. Cir. 1999) (internal citations omitted).

Summary judgment of obviousness is inappropriate here because Kyphon has raised genuine issues regarding each of the three prongs of an obviousness analysis. Kyphon established above that each and every element of the claim 1 is not found in either Dick or Kennedy. And, in any event, as explained below, there is no motivation to combine the two references. In addition, as described in Kyphon's Preliminary Injunction Application (Doc. X), there is overwhelming evidence that Kyphon's kyphoplasty technique experienced commercial success and satisfied a long-felt but unmet need, and has been met by strong praise from those of ordinary skill in the art. [Kyphon Ex. 35, Marks Decl. ¶¶ 31-34; Kyphon Ex. 36, Sandhu Decl. ¶ 18.]. Medtronic simply ignores the secondary indicia and instead suggests that this Court can invalidate claim 12 as obvious over Kennedy on summary judgment. Without considering such fact-intensive issues, summary judgment of nonobviousness is not appropriate. *See Rockwell*, 147 F.3d at 1366-67 (holding that genuine issues of material fact relating to secondary considerations preclude determination of obviousness on summary judgment and noting that, in resolving a summary judgment motion, inferences may not be drawn against the nonmovant and adverse credibility determinations may not be made); *Monarch Knitting Machinery Corp. v. Sulzer Morat GMBH*, 139 F.3d 877, 886 (Fed. Cir. 1998) (vacating the district court's grant of summary judgment based on obviousness and remanding for further proceedings because the record evidence raises genuine issues of material fact concerning the content of the prior art as well as several secondary considerations); *Pro-Mold and Tool Co., Inc. v. Great Lakes Plastics,*

Inc, 75 F.3d 1568 (Fed. Cir. 1996) (holding that genuine issues of material fact exist regarding the commercial success of invention and noting that it was error as a matter of law for district court not to provide reasons for apparently discounting Plaintiff's evidence of secondary considerations).

IX. OLERUD DOES NOT ANTICIPATE THE '404 PATENT

Olerud is an article that describes the use of a significant external hardware device in an open procedure to attempt reduction of traumatic vertebral burst fractures. [Kyphon Ex. 58, Mathis Depo. Tr. at 96:5-16.] The disclosed procedure is used for treating people who break their backs in car crashes and other traumatic accidents. [Kyphon Ex. 35, Marks Decl. ¶ 44.] It involves surgically opening up large parts of the back to access the spine directly and implanting a large metal device in several vertebrae surrounding the fractured vertebra, which is used to reduce and stabilize the fractured bone. The Olerud procedure is far removed from the minimally invasive kyphoplasty procedure claimed by the '404 patent.

Like Dick, the first step of Olerud's surgical intervention is the reduction of a compressed vertebra with a complex external mechanical device, a Posterior Segmental Fixator ("PSF") (shown below), that screws into the healthy vertebrae surrounding the fractured vertebrae. The PSF leverages against the healthy vertebrae to pull the two cortical faces of the fractured vertebra apart, to reduce the fracture and put the spine back into alignment. [Kyphon Ex. 35, Marks Decl. ¶ 45.] Olerud specifically explains that it is the PSF that achieves reduction.[21] [*Id.*] This reduction results in creating the initial "defect" in the fractured vertebra, when the cortical plates are leveraged apart. And, it is only then – after a void is already created – that a surgeon drills into the vertebrae and inserts a curved punch (probe). The curved punch is used to further reduce the fracture "if possible," as explained by Olerud.

The steps of Olerud can be summarized as follows:

[21] Olerud thus makes it explicit that reduction does not equate with compaction because the PSF reduces the fracture without compacting anything. This undisputed distinction is critical to the anticipation analysis here because the '404 patent requires a specific type of compaction –

1. A large part of the back is accessed in a highly invasive, open procedure.

2. A large metal device, PSF, pictured below, is attaching to the vertebrae above and below the fractured vertebra.

3. Two handles attached to the healthy vertebrae surrounding the fractured vertebra are levered towards each other to reduce the fractured vertebra in the middle by moving the end plates away from one another.

4. Screws attached to the healthy vertebrae are turned to achieve further reduction.

5. A hole is then drilled into the pedicle of the fractured vertebrae to access the void created by the PSF when the cortical end plates were leveraged apart.

6. A curved punch is introduced into the void to push away any debris.

7. Bone paste is then pressed into the void created by the PSF.

8. The PSF remains in the patient's back after the procedure is completed.

Olerud's passing mention of the possible use of a "curved punch" to attempt additional reduction of a fractured vertebrae does not teach compacting bone marrow to increase the volume of an initially formed passage. Also, its use of bone graft paste "pressed" into the vertebra, as with the Dick reference, does not describe the filling of a cavity with a "flowable material capable of setting to a hardened condition."

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formation of an initial passage in bone marrow that is subsequently increased in volume by compaction.

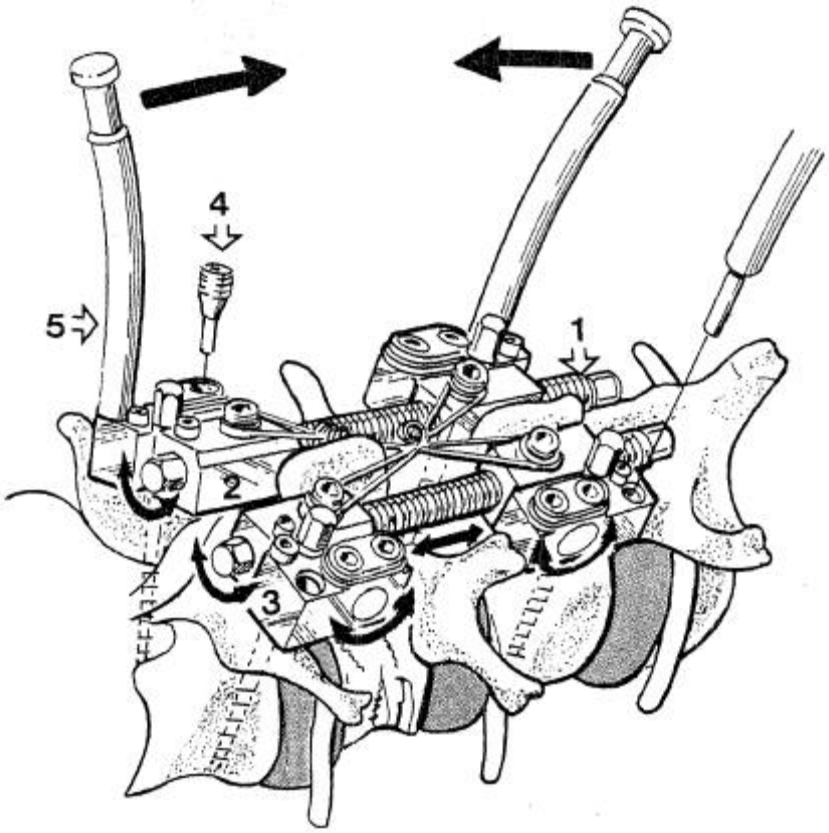

FIG. 1. The posterior segmental fixator (PSF). The device consists of two reversed units. Each unit is composed of one threaded rod (1). On this rod two bolt grips (2) are movable in relation to each other as well as to two screw grips (3) that surround the pedicular screws. The components are locked into each other by conical screws (4). With the special handles (5), the deformed vertebral body can be reduced to normal height and correct lordosis.

Thus, there are two limitations of claim 1 of the '404 patent missing from Olerud that preclude granting summary judgment of anticipation:

- compacting bone marrow to increase the volume of said passage, and
- filling the passage with a flowable material capable of setting to a hardened condition

A. Olerud Does Not Disclose "Compacting the Bone Marrow to Increase the Volume of Said Passage"

As with Dick and Kennedy, Olerud's movement of a curved punch through the fractured vertebra does not increase the volume of any initially formed passage.

Medtronic alleges that Olerud's drilling of a passage through the pedicle into the vertebral body meets the "forming a passage" limitation of claim 1. [Medtronic Ex. 1, Mathis

Decl. at 17; Kyphon Ex. 58, Mathis Depo. Tr. at 93:23-94:3.] But, it is only after the PSF created void already exists that the surgeon drills into the vertebra and inserts a curved punch. The punch is used, if possible to further reduce the end plates and anterior wall of the vertebra. [Medtronic Ex. 1-O, Olerud at 47; Mathis Depo. Tr. at 94:9-12.] Olerud does not refer to the punch compacting or compressing bone in any location. [Kyphon Ex. 58, Mathis Depo. Tr. at 94:13-19.] In addition, even assuming that the punch compacts the bone fragments as it pushes them back into place inside the vertebral body, there is nothing to suggest that it necessarily and inevitably also compacts the bone in the passage that the surgeon drilled through the pedicle to gain access to the PSF-created defect. [*Id.*, Mathis Depo. Tr. at 95:4-10, 95:24-96:4.] Even in Figure 3 of Olerud, below, which shows the probe reducing the fracture by pushing on the endplates (i.e., the top and bottom) of the vertebra in the void created by the PSF, there is no indication that the punch even touches the walls of the passage in the pedicle or anywhere else, nor that the punch necessarily and inevitably presses against bone with such force that the bone marrow is compacted and the volume of the passage is thereby increased. Kyphon's expert, Dr. Marks, explains that it does not. [Kyphon Ex. 35, Marks Decl. ¶ 46.]

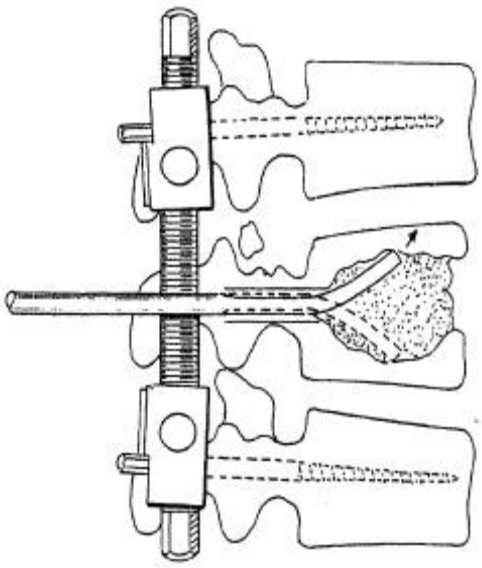

FIG. 3. With a transpedicularly introduced punch, further reduction of fragments in the vertebral body can be reduced. The defect in the vertebra is then filled with a graft in the form of bone paste.[8,13]

B. Olerud Does Not Disclose "Filling the Passage With a Flowable Material Capable of Setting to a Hardened Condition"

Olerud discloses only bone graft/bone paste as the filling material. As explained above with respect to the Dick reference, bone graft/bone paste is neither "flowable" nor "capable of setting to a hardened condition." Even Olerud describes bone graft/paste as being "pressed into the vertebra," which is not a description used for something that is flowable. [Medtronic Ex. 1-O, Olerud at 47; Kyphon Ex. 35, Marks Decl. ¶ 47.]

C. Olerud Does Not Teach Filling the Claimed "Passage"

In addition, it is the void resulting from the PSF reducing the fracture, as further reduced by the punch (if at all), that is filled in Olerud, not the passage in the pedicle that is created to access the PSF-created void. The void that is filled in Olerud thus is not created by increasing the volume of the initially formed passage, which is required by claim 1 of the '404 patent. [*Id.*]

For all of these reasons, summary judgment of anticipation based on Olerud is not appropriate.

X. ROMBOLD DOES NOT ANTICIPATE THE '404 PATENT

Medtronic filed its summary judgment of invalidity based on Rombold on October 28, 2006 – twelve days after filing its initial invalidity motion and eight days after Dr. Mathis signed his supplemental declaration opining on Rombold. Rombold is no better than Medtronic's other prior art. Kyphon addresses Rombold here, instead of waiting the additional time to which it is entitled to file an opposition, because Rombold suffers from the same defects as Medtronic's other asserted prior art.

Rombold's teaching adds nothing new to, and in fact is even more lacking than, the prior art previously relied upon by Medtronic. Rombold: (1) does not teach forming a passage in bone marrow; (2) does not teach any compaction of bone marrow much less compaction whereby the initial passage is enlarged in volume; (3) fills a cavity resulting from fracture reduction, not the claimed passage; and (4) discloses filling a void with bone graft, which as established above, is neither "flowable" nor "capable of setting to a hardened condition."

The Rombold article, like Kennedy, discloses treatment of depressed fractures of the tibial condyles. Instead of forming a passage in bone marrow,[22] Rombold teaches inserting a curette (probe) through the ***fracture line*** below the level of the depressed fragments to reduce the fracture. Rombold thus does not teach using the probe to compact bone marrow in any sense, whether to increase the volume of the passage or otherwise. Instead, the probe is used as a lever to rotate and move the depressed fragments upward until they form the best possible semblance of the normal plateau - their pre-fractured position.[23] The cavity resulting from lifting the depressed fragments is filled by packing it with bone graft.[24] Because the bone graft takes considerable time to vascularize (an average of 4.8 months before the fracture site is full weight bearing, according to the article), the procedure requires the use of extensive metal hardware (bolts, washer and nuts, and plates). [Kyphon Ex. 44, Rombold at 787; Kyphon Ex. 58, Mathis Depo. Tr. at 123:6-123:10; 129:11-130:9.]

The steps of Rombold can be summarized as follows:

1. A long incision is made in the skin extending from the upper pole of the patella (knee cap) down to the mid-shaft of the tibia (middle of the larger bone of the lower leg).
2. A curette (probe) is inserted through the fracture line below the level of the fractured fragments.
3. By using the probe as a lever, the fragments are rotated and teased upward until they form the best possible semblance of their original position.
4. A tibial bolt is drilled through the last and most stable fragment and the lateral cortex.
5. Through a lateral stab wound, a washer and nut are tightened to the bolt through the cortex (the incision is left open to allow further tightening in the procedure).
6. The cavity resulting from elevating the plateau fragments is filled by packing it with bone graft.

[22] Medtronic's invalidity motion based on Rombold, as did its initial motion, describes bone marrow inconsistently with the Delaware Court's construction, which it elsewhere says it accepts for purposes of this analysis [Medtronic Ex. 24, Delaware Litigation May 16, 2005 claim construction order at 12 defining "bone marrow" as "a combination of the connective tissue and the cancellous bone framework inside a bone; Medtronic's second summary judgment memorandum at 3 (Medtronic Statement of Facts No. 2.]

[23] Rombold notes that "[a]n attempt should be made to reconstruct the plateau slightly higher than normal to allow for settling." [Kyphon Ex. 44, Rombold at 784.]

[24] As Rombold states, "In most cases, a very considerable cavity was left under the articular plate after the fragments had been elevated." [*Id*., Rombold at 784.]

7. A longitudinal strut plate is applied at this point and the plate must be long enough to permit three or four screws to be placed in the tibial shaft below the fracture.

8. A short second plate bent to the horizontal contour of the tibial condyle may be used to maintain a badly shattered plateau.

9. The strut plate is then secured to the tibia shaft with three or four screws

Rombold's disclosure is nowhere near the minimally invasive kyphoplasty techniques of the '404 patent - forming a passage into the marrow, compacting the bone marrow to increase the volume of the formed passage and thereby creating a cavity that is then filled with a flowable material that hardens to support the reduced vertebrae. [Kyphon Ex. 35, Marks Decl. §§ 65-67.] In fact, all three limitations of claim 1 of the '404 patent are missing from Rombold, precluding summary judgment of anticipation:

- forming a passage in the bone marrow
- compacting bone marrow to increase the volume of said passage, and
- filling the passage with a flowable material capable of setting to a hardened condition

A. Rombold Does Not Disclose "Forming a Passage in the Bone Marrow"

Rombold does not teach the formation of a passage into bone marrow. For the "forming" step Medtronic relies upon Rombold's teaching of inserting a curette through the fracture line (breaks or spaces in the fractured bone). [Kyphon Ex. 44, Rombold at 784; Kyphon Ex. 58, Mathis Depo. Tr. at 116:24-117:21.] The fracture line is not created by the surgeon or formed by the surgeon in any other way. Instead, it is a space created when the bone broke. [Kyphon Ex. 58, Mathis Depo. Tr. at 117:19-22; Kyphon Ex. 35, Marks Decl. ¶ 66.] The first limitation of claim 1 of the '404 patent is thus wholly missing.

B. Rombold Does Not Disclose "Compacting the Bone Marrow to Increase the Volume of Said Passage"

As with the other references relied upon by Medtronic, Rombold's use of a probe to reduce the fracture does not increase the volume of any initially formed passage – in fact, there is no initially formed passage. Moreover, there is no suggestion in Rombold that the fracture line increases in size by any mechanism as a result of the procedure. Thus, Rombold does not teach

the sequential steps of: (1) forming a passage into bone marrow and (2) subsequently increasing the volume of *that* passage. [Kyphon Ex. 35, Marks Decl. ¶ 65.]

Rombold makes no mention of compaction – the reference does not even contain the term. [Kyphon Ex. 58, Mathis Depo. Tr. at 120:20-121:17.] And, Medtronic's expert, Dr. Mathis, never opines that Rombold teaches compaction. [*Id*., Mathis Depo. Tr. at 121:18-21.] The passage Medtronic cites for this limitation instead describes reduction – moving fractured bone back into its pre-fractured position. [*Id*., Mathis Depo. Tr. at 120:8-19.] And although Dr. Mathis testified that the fracture line, the initially formed passage according to Medtronic, could be enlarged, he did not opine that it is necessarily and inevitably enlarged based on Rombold. [*Id*., Mathis Depo. Tr. at 117:23-118:19.] The absence of compaction in Rombold further highlights the difference between "reduction" and "compaction." A physician can do one, both, or neither. Rombold reduces, but the '404 patent claims require compacting bone and doing so in a specific way – specifically, compacting the passage that the physician initially formed into the bone to be operated on.

C. Rombold Does Not Disclose a "Flowable Material Capable of Setting to a Hardened Condition"

Rombold describes only bone graft being packed into the cavity resulting from reduction. As explained above with respect to the Dick reference, bone graft is neither "flowable" nor "capable of setting to a hardened condition." [Kyphon Ex. 35, Marks Decl. § 68-70.] Like Dick, Rombold describes the cavity being completely filled[25] by "packing" it with bone graft—again not a term to be used with something that is "flowable."[26] [Kyphon Ex. 44, Rombold at 785.]

[25] Rombold's use of the term "*completely* filled" makes it clear that something can be "filled" to different degrees and that a modifier is necessary to indicate the desired degree. [Kyphon Ex. 44, Rombold at 785.]

[26] Dr. Mathis testified that because Rombold describes something that is "blenderized," "[i]t appears to me that [Rombold] would like to have it flowable." [Kyphon Ex. 58, Mathis Depo. Tr. at 122:22-123:5.] But, he did not testify that it necessarily and inevitably had to be flowable. [*Id*.]

D. Rombold Does Not Make Obvious Claim 12 of the '404 Patent

Rombold fails to make obvious claim 12 for the same reasons as Kennedy. Like Kennedy, Rombold is directed to fractures of the tibia, and does not refer anywhere to the spine or vertebra. [Kyphon Ex. 58, Mathis Depo. Tr. at 123:11-18.] Thus, it cannot anticipate claim 12. Medtronic alleges that Rombold renders claim 12 obvious in view of the Dick reference.

As with Kennedy, however, there is no motivation to combine Rombold with Dick. [Kyphon Ex. 35, Marks Decl. ¶ 35.] Medtronic relies on the Dick reference to allege that one of ordinary skill would have known to apply the Rombold procedure on a vertebral body, but that is far from true. At most, the Dick reference says that the principle of filling a bone defect resulting from an injury, through a cortical window, *can be* used in vertebral compression fractures. It does not teach that any and every procedure for treating tibial fractures, such as the Rombold procedure, should be used on vertebral compression fractures. Also, Dick refers to a cortical window in the tibia or vertebra, but Rombold makes not mention of a cortical window. And, again, Medtronic does not address the significant secondary indicia of nonobviousness, which it must to prove that claim 12 is obvious.

E. Kyphon's FDA Filings Do Not Support Medtronic's Rombold Arguments[27]

Not only are Kyphon's FDA filings irrelevant to the invalidity analysis, but they are also not to the contrary. Kyphon's submissions to the FDA compared bone reduction using conventional bone tamps with reduction using its commercial kyphoplasty devices ("KyphX IBTs"). The critical point is that these FDA submissions ***are not referring to Kyphon's patents or the procedure they describe.*** Indeed, they never even mention Kyphon's patents or whether Rombold or any other reference discloses forming a passage in bone marrow and subsequently increasing the volume of that passage by compaction. The FDA submissions were filed ***nine***

years after the '404 patent's effective filing date, nine years after the relevant date for an invalidity analysis.[28]

Each of the cover letters to Kyphon's FDA submissions told the FDA that the KyphX IBT was "new." [Medtronic Ex. 29-B, Kyphon April 3, 1998 FDA Submission at KY 117295.] And, Kyphon's initial submission even included the Rombold reference itself. [*Id.*, FDA submission at KY 117467.] Thus, this certainly could not be an admission that Rombold was the same thing as the KyphX IBT. Moreover, in portions of the submissions not cited by Medtronic, Kyphon repeatedly told the FDA that the KyphX IBT was substantially equivalent ***in certain respects*** to three different categories of prior art devices, only one of which included conventional bone tamps of the type shown in Rombold. [*Id.*, April 3, 1998 FDA Submission at KY 117307-08; Medtronic Ex. 29E, Kyphon July 1, 1998 FDA Submission at 2-3.] Furthermore, the purpose of such FDA filings is to address the substantial equivalence of *efficacy and safety only*, not to suggest that it is all the same technology. 21 C.F.R. 807.100(b). Because Kyphon's device combined and added to the attributes of three different categories of devices, its device was indeed "new." [*Id.*][29] In addition, Kyphon also told the FDA that its device was different in critical respects from conventional bone tamps like Rombold, especially because it could be used

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[27] Medtronic only addresses Kyphon's FDA filings in its motion regarding the Rombold reference.

[28] The priority filing date of the '404 patent is in 1989. [Medtronic Ex. 1-C, '404 patent; Medtronic Ex. 1-D, '888 patent.] Kyphon filed its first 510(K) application in 1998. Moreover, while Medtronic implies that Kyphon should have disclosed Rombold to the Patent Office, it presents no evidence that anyone involved in the prosecution of the '404 patent even knew about Rombold.

[29] Medtronic ignores Kyphon's description of prior art bone tamps as being able to "reduce fractures and/or create voids." [Medtronic Ex. 29-B, Kyphon's 1998 510(K) FDA Submission at KY 117442.] The description is in the aggregate because "compaction" is different from "reduction" and a physician can do one, both, or neither. [Kyphon Ex. 35, Marks Decl. ¶¶ 40,52.] Thus, in statements where Kyphon draws parallels between the KyphX IBT and conventional bone tamps, Kyphon describes them in the aggregate. Kyphon never stated that any particular prior art bone tamp had all the same characteristics as the KyphX IBT (or vice versa).

percutaneously. [Medtronic Ex. 29-B, Kyphon's April 3, 1998 FDA Submission at KY 11704-05, KY 117708.] Medtronic ignores these sections.

In any event, Kyphon's patents are nowhere near as generic as the bone tamp description in the FDA submissions. Instead, the patents focus specifically on a particularly claimed method of compacting in a certain way: (1) forming a passage in bone marrow, and (2) subsequently enlarging the volume of that passage by compaction. Kyphon's FDA submissions say nothing at all about the procedure claimed in the '404 patent.[30]

XI. CONCLUSION

As Dr. Marks' and Dr. Sandhu's declarations, and the other relevant evidence cited by Kyphon demonstrates, at a minimum, that there are numerous genuine issues of material fact connected with all four references relied upon by Medtronic – Dick, Kennedy, Olerud, and Rombold. The references' disclosures themselves, however, establish that none comes close to anticipating the claimed invention, and Medtronic does not do a proper obviousness analysis. Kyphon therefore respectfully requests that the Court deny Medtronic's motions for partial summary judgment.

[30] The portion of Kyphon's FDA submission cited on p. 13 of Medtronic's brief is not to the contrary. This statement says nothing about forming a channel in bone marrow or compacting the marrow to increase the volume of that passage.

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CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of November 2006, I electronically filed

KYPHON'S COMBINED OPPOSITION TO MEDTRONIC'S MOTIONS FOR PARTIAL SUMMARY JUDGMENT OF INVALIDITY OF U.S. PATENT NO. 5,108,404 BASED ON THE KENNEDY, OLERUD, DICK, AND ROMBOLD REFERENCES

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